



42 CFR Part 2 Public Listening Session

January 31, 2018

Substance Abuse and Mental Health Services
Administration
U.S. Department of Health & Human Service



Agenda



- ➔ Introductory/housekeeping comments: Kim Johnson, Director, Center for Substance Abuse Treatment
- ➔ Welcoming remarks: Dr. Elinore McCance-Katz, Assistant Secretary for Mental Health and Substance Use
- ➔ Background on 42 CFR Part 2: Kim Johnson, Director, Center for Substance Abuse Treatment
- ➔ Public comments: In person and via Webcast
- ➔ Conclusion

Housekeeping

- ➔ Restrooms are located outside this room around corner
- ➔ A cafeteria is located across the hall on this floor
- ➔ If you leave the building or walk back past the security desk, you will need to be escorted back in
- ➔ Meeting is being recorded to capture comments and questions and facilitate follow up
- ➔ Participants in room are asked to mute their phones
- ➔ Please state name/title/organization before speaking
- ➔ If on audioconference/Web: Prior to pressing *1 please unmute your phone and state your name when prompted

Welcoming Remarks



- Assistant Secretary for Mental Health and Substance Use
- Dr. Elinore McCance-Katz

21st Century Cures Act



SEC. 11002. CONFIDENTIALITY OF RECORDS. Not later than 1 year after the date on which the Secretary of Health and Human Services (in this title referred to as the “Secretary”) first finalizes regulations up-dating part 2 of title 42, Code of Federal Regulations, relating to confidentiality of alcohol and drug abuse patient records, after the date of enactment of this Act, **the Secretary shall convene relevant stakeholders to determine the effect of such regulations on patient care, health outcomes, and patient privacy.**

Background



- Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. §1175) and Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (42 U.S.C. §4582) authorized confidentiality for patient records
- Initial part 2 regulations promulgated on July 1, 1975
- Substantive revisions: 1987, 2017

Background -continued



- Congress noted discrimination associated with substance use disorders and fear of prosecution deterred people from entering treatment
- Statute authorizing 42 CFR part 2 intended to protect the confidentiality of substance use disorder records.
- Persons with substance use disorders continue to be subject to a host of negative reactions including discrimination and harm to their reputations and relationships.

42 U.S.C. § 290dd-2

- **This statute is the basis for 42 CFR part 2 and cannot be changed except by Congress**
- “Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States” shall be confidential
- May be disclosed as permitted by prior written consent of the patient
- Subject to certain exceptions/exclusions

42 U.S.C. § 290dd-2, continued



→ Exceptions to consent requirement:

- To medical personnel to the extent necessary to meet a bona fide medical emergency
- To qualified personnel for the purpose of conducting scientific research, management or financial audits, or program evaluation but individual patients cannot be identified by those personnel in any report or otherwise disclosed
- If authorized by a court order showing good cause (e.g., need to avert a substantial risk of death or serious bodily harm)
- Except as authorized by court order, no record may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient

42 U.S.C. § 290dd-2, continued

→ Statute does not apply to:

- Exchange of records within the Department of Veterans Affairs or between the VA and the Uniformed Services. VA to issue regulations and coordinate with HHS
- Reports under state law of suspected child abuse or neglect

→ Penalty: Violations fined under Title 18 of US Code

→ Instructs HHS Secretary to promulgate regulations


→ These regulations known as “42 CFR part 2” or “part 2”

Background - Medical Privacy



- ➔ Part 2 aligns with Health Insurance Portability and Accountability Act (HIPAA) to extent currently feasible
- ➔ Substance use disorder patient records and information may be subject to HIPAA, part 2, and state laws
- ➔ If both HIPAA and part 2 apply, follow the law that is more stringent
- ➔ 42 CFR 2.20: If a disclosure is permitted under part 2 but prohibited under state law, neither the statute or regulations authorize violation of state law. No state law may either authorize or compel any disclosure prohibited by part 2.

Why Did SAMHSA Recently Revise 42 CFR Part 2?

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- The last substantive update was 30 years ago.
 - Significant changes have impacted health care delivery since 1987:
 - New models of integrated care that rely on information sharing to improve patient safety
 - Electronic infrastructure for managing and exchanging information
 - New focus on performance measurement
 - SAMHSA wanted to ensure that patients with substance use disorders have the ability to participate in, and benefit from new integrated health care models without fear of putting themselves at risk of adverse consequences

Comments Submitted During the Revision of 42 CFR part 2



- 2014 Listening Session –
<https://www.samhsa.gov/about-us/who-we-are/laws-regulations/public-comments-confidentiality-regulations>
- February 9, 2016 NPRM (81 FR 6987) -
<https://www.regulations.gov/document?D=HHS-OS-2016-0005-0001>

2017 Final Rule (82 FR 6052)



- Final rule published in the *Federal Register* on January 18, 2017
- *Federal Register* effective date initially scheduled for February 17, 2017
- *Review by the administration resulted in a revised effective date of 3/21/2017*
- Emphasized the need to balance patient protections with enhanced information exchange and data sharing
- <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0377>

2017 Final Rule (82 FR 6052)



Among the numerous changes made to the rule:


- ➔ Entire rule updated to apply to electronic as well as paper exchange of patient identifying information
- ➔ Definitions (§ 2.11) – revised/added several definitions, e.g., added “Treating provider relationship”
- ➔ Applicability (§ 2.12) – Restrictions apply to information received from “Other lawful holders”
- ➔ Confidentiality restrictions and safeguards (§ 2.13) – added List of Disclosures requirement

2017 Final Rule (82 FR 6052), continued



- ➔ Consent requirements (§ 2.31) – e.g., permits a general designation in the “To Whom” section of the consent
- ➔ Medical emergencies (§ 2.51) – Revised consistent with statutory language
- ➔ Research (§ 2.52) – E.g., more closely aligned with HIPAA and the Common Rule
- ➔ Audit and evaluation (§ 2.53) – Permits audits and evaluations to meet certain CMS requirements

Supplemental Notice of Proposed Rulemaking (SNPRM)



- ➔ SNPRM published in the *Federal Register* on January 18, 2017
- ➔ Comments on proposed rule in 2016 highlighted varying interpretations of the rule's restrictions on use and disclosure of patient identifying information by lawful holders and their contractors and subcontractors for purposes of carrying out payment, health care operations, and other health care-related activities
- ➔ Commenters noted that third-party payers, other lawful holders of patient identifying information, and their contractors and subcontractors and legal representatives play a critical role in the provision of health care services

SNPRM, continued

- ➔ The SNPRM provided SAMHSA the opportunity to obtain additional public comment about changes that would recognize the important role of contractors, subcontractors and legal representatives
- ➔ The SNPRM proposed that, consistent with part 2 consent provisions, lawful holders of patient identifying information would be allowed to further disclose the minimal information necessary for specific payment and health care operations activities such as claims processing, business management, training, and customer service. This list is similar to the activities described in the HIPAA Privacy Rule's definition of the terms “payment” and “health care operations,” although SAMHSA did not adopt these definitions in their entirety

SNPRM, continued



- Proposed changes to Audit and Evaluation provisions to expressly address further disclosures to contractors, subcontractors, and legal representatives, and to permit audits and evaluations of “other lawful holders of patient identifying information”
- Sought comment on whether to add an abbreviated notice to accompany re-disclosure for use in certain circumstances where a shorter notice may be warranted (e.g., for electronic health record systems)

Final [SNPRM] Rule

- ➔ Permits lawful holders to disclose or re-disclose patient identifying information to their contractors, subcontractors and legal representatives for purposes of carrying out the lawful holder's payment and health care operations activities, when patient consents to disclosure for those activities
- ➔ Includes an optional abbreviated notice on prohibition on re-disclosure (required to accompany the disclosure of patient identifying information): *"Federal law/42 CFR part 2 prohibits unauthorized disclosure of these records."*
- ➔ Finalizes audit and evaluation provisions
- ➔ Made some minor technical amendments to other part 2 provisions

SAMHSA's Priorities



- Patient privacy remains an important concern. However, equally important is the need for:
- Providers to be able to share information to improve patient treatment
 - Patients to benefit from integrated care
 - Patients, providers, and the overall health system to benefit from use of new technologies and approaches (e.g., Health Information Exchanges, Electronic Health Records, and Multi-payer Claims Databases)
 - Greater alignment of part 2 with HIPAA


SAMHSA's Discussion Priorities For Today



Given the constraints of the governing statute:

- ➔ How could SAMSHA revise part 2 to ensure it adequately addresses “patient care, health outcomes, and patient privacy?”
- ➔ What specific changes, if any, should SAMHSA make to the regulatory text of part 2?
- ➔ What regulatory changes or policy clarifications should SAMSHA consider making to further align part 2 with HIPAA and state privacy laws/ regulations?
- ➔ What subregulatory guidance would be helpful?

Public Comments Guidelines

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- We will adhere strictly to the 3-minute per comment timeframe
 - Moderator will notify speakers when their 3 minutes are up
 - We will take in-person comments first and then take comments over the phone
 - Speakers should state their name, title and, if applicable, their organization or agency
 - Please state name/title/organization before speaking
 - If on audioconference/Web: Prior to pressing *1 please unmute your phone and state your name when prompted
 - All comments, including those provided orally at this meeting, should be submitted in writing. As indicated in the *Federal Register* announcement, written comments will be accepted through Feb. 28, 2018.
 - Meeting is being recorded to capture comments and questions and facilitate follow up

Closing Remarks Slides Follow



Closing Remarks



- SAMHSA welcomes written comments on effect of Part 2 on patient care, health outcomes, and patient privacy
- We look forward to working with stakeholders and HHS partners on implementation of part 2 to ensure benefits for patients and reduced regulatory burdens for providers, payers, researchers and others
- SAMHSA will review all comments submitted for this meeting on part 2 issues
- SAMHSA appreciates the participation and interest of everyone today

Written Comments

Written comments may be submitted:

- ➔ Electronically: PrivacyRegulations@SAMHSA.hhs.gov
- ➔ Regular, Express or Overnight Mail, or Hand Delivery or Courier: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services, Attn: Mitchell Berger, SAMHSA, 5600 Fishers Lane, Room 18E89C, Rockville, Maryland 20857.
- ➔ Receipt of comments will not be acknowledged due to an expected high volume.



THANK YOU
Questions:

PrivacyRegulations@samhsa.hhs.gov

